

Application No. 10/563,996
Amendment Dated August 5, 2008
Reply to Office Action of May 15, 2008

REMARKS

The Office Action mailed May 15, 2008, has been carefully considered by Applicant. Reconsideration is respectfully requested in view of the foregoing claim amendments and the remarks that follow.

Allowable Subject Matter

Claims 45 and 46 are allowed. Claims 26, 27 and 32 are indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 26, 27 and 32 are hereby retained in dependent form and depend from claims that are also believed allowable for the reasons stated hereinbelow.

Claim Rejections

Claims 25, 28-31, 33, 34 and 44 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kairis EP Patent No. 0145176 in view of Yomtov U.S. Patent No. 4,360,615. Claim 24 is rejected under 35 U.S.C. §103(a) as being unpatentable over Kairis '176 and Yomtov '615 and further in view of Masopust U.S. Patent No. 5,339,827.

Claims 25 and 44 are amended to indicate that the Applicant's treatment is non-invasive, and that the detector detects the skin impedance "responsive to the applied electrical impulses". Accordingly, the claimed treatment is non-invasive and is based on the application of electrical impulses through a pair of electrodes to the patient's skin, followed by the detection of the skin impedance responsive to such applied electrical impulses and the monitoring of the skin impedance for indicating when a particular responsivity is reached and when the necessary amount of treatment has been administered. The way in which detection and monitoring is achieved is by employing a detector producing output signals in the form of pulses whose duration represents the skin impedance, and a monitor which measures such duration for determining when to activate an indicator.

New dependent claims 47 and 48, relate to the feature of influencing the electrical impulses through changes in skin impedance. A basis for such claims is found on page 4, lines 18-20.

Application No. 10/563,996
Amendment Dated August 5, 2008
Reply to Office Action of May 15, 2008

The Examiner is objecting that the subject matter of claim 25 is obvious in relation to Kairis '176 in view of Yomtov '615. It is submitted that an accurate reading of Kairis '176 and Yomtov '615 does not lead to this view.

Kairis '176 teaches a treatment device having a housing 1, a pair of electrodes 2a, 2b, and an IC circuit 5 powered by a battery 7. In operation, the electrodes are placed in contact with the patient's skin and a current of "approximately 0.2 micro A flows through the electrodes". It is to be noted that this is a DC current and not a series of electrical impulses based on a repeatedly generated AC waveform. The resistance between the two electrodes decreases when the electrodes are located on a low resistance point, and such decrease activates either respective LEDs in an indicator 13 and/or a speaker 6 to indicate that a low resistance point has been found. Next, a switch 3 is depressed to produce an electric pulse. The Examiner has cited the passage on page 6, lines 14 to 18, as evidence of a repeated AC waveform but this is not what this passage discloses. This passage refers to a "piezo-current about 1 micro A" and "and electric pulse". This is not a disclosure of a repeated AC waveform (nor of a piezo-electric oscillator) but rather a disclosure of a single DC pulse of a particular amplitude. In fact, the entire text makes repeated references to "an electric pulse" and "the pulse" but nowhere discloses or suggests the application to the skin of repeated electrical impulses or a pulse train. Certainly, there is no suggestion anywhere in Kairis '176 of a repeatedly generated AC waveform.

Further, Kairis '176 does not disclose a number of other claimed features. Firstly, as discussed, the location of the low resistance point in Kairis '176 is based on the application of a constant DC current and an indication that the resistance between the two electrodes has decreased. It is only thereafter that a pulse is generated. Consequently, Kairis '176 does not disclose the detection of a predetermined level of responsivity based on detecting and monitoring skin impedance responsive to applied electrical impulses.

Next, as acknowledged by the Examiner, Kairis '176 also contains no disclosure of a detection arrangement according to the claims wherein the detector generates detection

Application No. 10/563,996
Amendment Dated August 5, 2008
Reply to Office Action of May 15, 2008

pulses whose duration represents skin impedance, and the monitoring means measures the duration of each pulse for activating the indicating means.

There are therefore considerable differences between Kairis '176 and the present invention.

Yomtov '615 concerns apparatus belonging to a completely different treatment field, both from the present invention, and also from Kairis '176, and this difference is especially significant. Yomtov '615 relates to a neural stimulating apparatus employing implanted stimulating elements, including an implanted cathode electrode 12, which is inserted into the epidural space in a spinal cord so that electrical pulses can be supplied to the nerves in the spinal cord for blocking signals to the brain. This is utterly contrary to the non-invasive techniques of the present invention (and also separately Kairis '176), and no expert in the medical field would consider applying techniques from an invasive treatment process in a non-invasive treatment process, such as that applied by the present invention. There are many reasons for this, not the least of which is that surgery is required for the implantation of treatment apparatus into the body, and such surgery is very delicate when implantation into the epidural space in the spinal cord is concerned; whereas the non-invasive technique of the present invention simply requires that the treatment device be held against the skin. The former process requires extremely precise and delicate application by highly qualified and skilled surgical experts, whereas the latter can be applied by ordinary trained personnel.

Aside from this, Yomtov '615 is in no way concerned with the treatment of clinical conditions via the skin, nor with the application of electrical impulses to the skin, nor with the detection of skin impedance. Rather, Yomtov '615 discloses a neural stimulating system in which a cathode electrode 12 is implanted in the epidural space in a spinal cord and an anode electrode 18 (or case 20 of the system) is also implanted, and in which a microprocessor 26 controls the delivery of constant current output pulses through the implanted cathode electrode. The neural stimulating system is also provided with impedance monitoring apparatus 30, whose purpose is to monitor the impedance of the lead 14 connected to the cathode electrode 12, since scar tissue may build up around the

Application No. 10/563,996
Amendment Dated August 5, 2008
Reply to Office Action of May 15, 2008

electrode and reduce the connection of the electrode to the body. Accordingly, there is no disclosure or suggestion in Yomtov '615 of detecting skin impedance, only a disclosure of detecting the impedance of an electrical lead.

Furthermore, the impedance monitoring apparatus 30 monitors impedance by converting the constant current pulses supplied to the cathode electrode 12 into a constant voltage pulse 82 of fixed duration and amplitude dependent on the impedance of the cathode lead 14, and comparing such pulses with a ramped reference voltage 82, in order to count the number of the voltage pulses that are greater in magnitude than the ramped reference voltage. The number determined represents the impedance of the cathode lead 14.

Therefore, Yomtov '615 contains no disclosure of pulses whose duration represents any form of impedance, still less the disclosure of a detector generating pulses whose duration represents skin impedance. Since the pulses in Yomtov '615 are all of the same duration, it makes no sense to measure the duration. There is therefore nothing in Yomtov '615 resembling the monitoring means of the present invention, which measure the duration of each pulse of the detector output signal for determining when to trigger an indicator to generate a first indication and a second indication representing different stages of treatment.

As already mentioned, a medical expert would not consider combining Kairis '176 describing a non-invasive form of treatment and Yomtov '615 describing an invasive treatment with implanted electrodes. However, even if the Examiner is minded to overlook this fact, it is still clear from the above description that a combination of Kairis '176 and Yomtov '615 does not yield the features of the present invention as set out in claim 25, since neither of these documents discloses the repeated generation of an AC waveform for applying electrical impulses through a pair of electrodes to a patient's skin, neither of them discloses the application of electrical impulses for determining when a predetermined level of skin responsivity is reached, and neither of them discloses a detection arrangement in which detector output signals are in the form of pulses whose duration represents skin impedance and in which this duration is measured for determining both level of responsivity and when a predetermined treatment has been administered.

Application No. 10/563,996
Amendment Dated August 5, 2008
Reply to Office Action of May 15, 2008

Accordingly, it is submitted that the present invention as defined in claim 25 is patentably distinguished from the cited references. Claim 44 corresponds with claim 25 and, therefore, the same arguments apply.

Claims 24, 26-34 and 47 are dependent on claim 25 and claim 48 is dependent on claim 44 and are therefore believed allowable also.

Conclusion

The present application is thus believed in condition for allowance. Such action is respectfully requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP



Peter T. Holsen
Reg. No. 54,180

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, WI 53202
Telephone: (414) 271-7590
Facsimile: (414) 271-5770